Tech Talk

Single-Use Technology – Achieving Smooth Transitions into Your Operations

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This article provides guidelines for the assessment of single-use technology and recommends plans for a smooth and speedy integration of single-use technology into your operation. We present an implementation model to switch from stainless steel tanks to bioprocess containers (BPC). While the article focuses on BPC, the techniques can be applied to other single-use components or assemblies.

What are the benefits?

The benefits are simple - switching from stainless steel tanks to BPCs increases efficiency and flexibility while decreasing capital costs. Achievement of these benefits depends on a strong analysis for your particular situation and a well executed implementation program. Conducting the right activities at the appropriate time is critical for success. The project plan should be all encompassing from the beginning and minimize surprises throughout.

Get started with an effective follow through

A comprehensive implementation process is a key factor in achieving these benefits. For this process to be effective, input from several company functions are required. This can be assured if the project includes the following elements:

1. Define a multifunctional team with a project manager knowledgeable in BPCs.
2. Develop a project plan covering all affected areas in the company's operations.
3. Decide on vendors that can best support your initiative.
4. Plan for and conduct testing to qualify the switch in the operation.

It is important to assign a project manager to head the BPC implementation team. The project manager should have sufficient knowledge about BPCs to work with the implementation team to define the scope of the project, the needs of the company, and the processes/applications where BPC implementation is most beneficial.

The mechanics of getting it done right the first time

When defining the scope of the project, it is necessary to examine the specific needs of the company. Though BPCs allow for cost savings by eliminating steam-in-place and clean-in-place operations, the investment needed to switch to BPCs may not make it feasible for every stainless steel tank to be replaced. It is important to involve as many area managers as necessary, along with quality and validation representatives, to determine which applications would most benefit from BPC implementation.

Once process applications have been earmarked for BPC implementation, the project team decides which BPC sizes and volumes will be used based on production needs. Taking into account available space in a facility is key to deciding upon BPC sizes. Regardless of the cost savings benefits that might come from implementation, if there is no available space in a facility to support a certain-sized BPC, then implementation is not possible. Furthermore, if the BPC is to be used in multiple areas and rolled or carried around, it is necessary to consider the feasibility

of doing this with the proposed size and volume BPC. Finally, when determining BPC volumes it is important to overestimate the maximum fill volume as overfilling BPCs is not recommended.

After production needs have been agreed upon, the implementation team's focus should shift towards determining specific bag requirements. Not all BPCs are created the same and as such a list of bag requirements specific to the proposed process should be formulated so that it can be presented to vendors. Among the requirements that need to be examined are the usage and tubing specifications that the BPC will be introduced into. For example, when looking at the process in which BPCs would be utilized, usage requirements would include filling strategy and whether the BPC is compatible with the proposed method of filling. Other usage requirements that must be studied prior to implementation are filtration requirements (i.e. whether the filters used in the process are compatible with the BPC) and whether a certain BPC will be used for a single application or multiple ones.

Since BPCs are usually introduced into a process rather than as stand alone entities, it is just as important to make sure that tubing requirements are also in line with the proposed operation. Tubing should be compatible with the flow rates, pressure, connections, and inlet/outlet configuration that will be present in the process as well as being the right length in order to be accessible. Tubing also needs to be compatible with the chemical and mechanical properties of the process as well as the temperatures, leachable standards, and biocompatibility of the process.

Deciding on vendors

Once the implementation team decides on their needs and specific BPC requirements it is time to bring those requirements to vendors to supply the team with the product. It is important to evaluate enough vendors to identity at least two that meet the implementation team needs. Having dual-sourced BPCs will buffer against vendor supply issues affecting the process. Another thing to consider when choosing vendors is the responsiveness and knowledge base of their staff. If you have to hold a vendor's hand during the purchase process, do not expect much help from them if anything goes wrong. Furthermore the chosen vendor should have the quickest turnaround time for engineering changes and should operate with corporate standards similar to those at your own company. Engineering change turnarounds between two and three weeks should prevent the implementation process from being dragged out due to vendor inadequacy. In addition, qualified local support from the vendor can mean the difference between a process being run on time or not.

Another consideration that must be made when evaluating vendors is the flexibility in BPC tote design. The ability for the vendor to add wheels or a temperature control jacket to a BPC tote to fit your facility needs is an important factor in the selection. While this flexibility can be considered anywhere in the vendor selection process, Figure 1 (see later section of article) identifies an optimum location in the timeline to do this evaluation.

Furthermore, if the BPC will be placed into a regulated process, it is important to evaluate the availability of validation and extractable testing data and endotoxin and particulate (EP) testing provided by the vendor. Qualification and validation testing can put a serious dent in your budget to the point where a vendor's willingness to provide that testing may make or break the decision to go forward with BPC implementation in your facility. Also, along with the above BPC testing, a vendor should be evaluated on their availability of appropriate USP and EP testing on all components.

Ultimately, though it is important to evaluate a vendor on the basis of many different conditions, the most important consideration should be placed on the quality of film and overall product provided by the vendor along with the functionality of the design in terms of your process.

Testing is a major factor

Once the primary and secondary vendors are selected, it is time to conduct the necessary testing in order to implement your new BPC into your process stream. While most vendors conduct contact layer testing for their specific containers, it is important that either your company or a contracted testing lab performs testing specific to the storage conditions, solutions and hold times that exist in your process. It is important that test conditions mirror the actual conditions that the BPC will encounter since temperature, the aggressiveness of the solution, and the organic content of the solution all affect the performance of the BPC and ultimately the proposed process into which it is being implemented. Since plastics can release soluble or insoluble materials into products, it is also necessary to conduct a technical assessment to identify the sources and amounts of these extractable chemicals.

An extractable testing program should be initiated to estimate the quantity of chemicals that can potentially leach from plastics into process streams by using model test solutions that bracket the process solutions. This bracketed approach generates a worst-case estimate for the maximum amount of extractables that could be concentrated within the product and evaluates the risk associated with the worst-case extractability findings. Other factors that must be controlled are maximizing the surface-to-volume ratio of the test container-solution combination and storing the containers for the actual time that will be used in production.

Bringing it all together

By developing a strong team and following a structured implementation timeline (like the one seen in Figure 1), disposable bioprocess containers can be effectively and efficiently implemented into a facility's operation with minimal surprises and disruptions.